CLAIMS:

1. A controlled release pharmaceutical delivery device which provides sustained or pulsatile delivery of a selected pharmaceutically active substance for a predetermined period of time, said device comprising;

- about 1 to 80% by weight covalently crosslinked water insoluble, water-swellable polymers; and

- about 1 to 75% by weight uncrosslinked, linear water soluble polymers.

2. The device of claim 1, wherein said uncrosslinked polymers are selected from cellulose ethers and their derivatives.

3. The device of claim 1, wherein said covalently crosslinked water in soluble polymers are selected from water swellable, high molecular weight cross-linked homopolymers and copolymers of acrylic acid.

4. The device of claim 3, wherein said covalently crosslinked water insoluble polymers are Carbopol resins.

5. The device of claim 2, wherein said cellulose ethers and their derivatives are selected from the group consisting of hydroxyethyl cellulose, hydroxypropyl methyl cellulose, ethylcellulose and hydroxypropyl cellulose.

6. The device of claim 3, wherein said crosslinked water insoluble polymer is selected from polymers of acrylic acid crosslinked with polyalkenyl alcohols and divinyl glycol and mixtures thereof.

7. The device of claim 1, wherein said device additionally comprises about 0.5 to 50% by weight of a coating material comprising anionic polymers based on methacrylic acid and methacrylic acid esters or neutral methacrylic acid esters with trimethylammonioethyl methacrylate chloride or cellulose esters.

8. The device of claim 1, wherein said device additionally comprises;

- up to about 35% by weight glidant;
- up to about 35% by weight lubricant; and
- up to about 95% by weight granulating and tableting aids.

9. A controlled release pharmaceutical delivery device which provides sustained or pulsatile delivery of a selected pharmaceutically active substance for a predetermined period of time, said device comprising;

- about 1 to 60% by weight of hydroxyethylcellulose;
- about 1 to 75% by weight of hydroxypropylmethyl cellulose;
- about 1 to 60% by weight of ethylcellulose;
- about 1 to 80% by weight of at least one Carbopol® resin;
- about less than 10% by weight of talc;
- about less than 10% by weight of magnesium stearate; and
- about less than 95% by weight granulating and tableting aids.

10. The device of claim 9, wherein said device additionally comprises about 1 to 80% of a pharmaceutically active agent.

11. The device of claim 10, wherein said pharmaceutically active agent is selected from the group consisting of diltiazem, buspirone, tramadol, gabapentin, verapamil, etodolac, naproxen, diclofenac, COX2 inhibitors, budesonide, venlafaxine, metoprolol, carbidopa, levodopa, carbamazepine, ibuprofen, morphine, pseudoephedrine, paracetamol, cisapride, pilocarpine, methylphenidine, nifedipine, nicardipine, felodipine, captropril, terfenadine, pentoxifylline, fenofibrate, flipizide, aciclovir, zidovudine, moclobemide, potassium chloride, lamotrigine, citalopram, cladribine, loratadine, pancrelipase, lithium carbonate, orphenadrine, ketoprofen, procainamide, ferrous sulfate, risperidone, clonazepam, nefazodone, lovastatin, simvastatin, pravachol, ketorolac, hydromorphone, ticlopidine, seligiline, alprazolam, divalproex and phenytoin.

12. The device as claimed in claim 1 wherein, said device additionally comprises one or more pharmaceutical excipients selected from the group consisting of lactose, silicone dioxide, sodium lauryl sulphate, calcium phosphate, calcium sulphate, silicified microcrystalline cellulose, geluciro® and compritol®.

~~13.~~ A method for making an extended release formulation of pharmaceutically active agents, said method comprising;

- blending about 1 to 80% pharmaceutically active agent with about 1 to 80% by weight covalently crosslinked water insoluble, water swellable polymers, and about 1 to 75% by weight uncrosslinked, linear water soluble polymers.

~~14.~~ A method for making an extended release formulation of pharmaceutically active agents, said method comprising;

- blending about 1 to 80% pharmaceutically active agent with about 1 to 70% by weight uncrosslinked, water soluble polymers to form a homogeneous blend;
- granulating said homogeneous blend with a granulating solution to form a wet mass of granules and kneading said wet mass;
- drying said wet granules to a loss on drying of about less than 5%;
- reducing said dried granules such that granule size is less than about 1400 microns;
- blending said milled granules with about 1 to 80% of a crosslinked polymer, about less than 5% of a glidant, and about less than 5% of a lubricant; and
- compressing the lubricated granules into tablets.

15. The method as claimed in claims 13 or 14, wherein said pharmaceutically active agent is selected from the group consisting of diltiazem, buspirone, tramadol, gabapentin, verapamil, etodolac, naproxen, diclofenac, COX2 inhibitors, budesonide, venlafaxine, metoprolol, carbidopa, levodopa, carbamazepine, ibuprofen, morphine, pseudoephedrine, paracetamol, cisapride, pilocarpine, methylphenidine, nifedipine, nicardipine, felodipine, captropril, terfenadine, pentoxifylline, fenofibrate, flipizide, aciclovir, zidovudine, moclobemide, potassium chloride, lamotrigine, citalopram, cladribine, loratadine, pancrelipase, lithium carbonate, orphenadrine, ketoprofen, procainamide, ferrous sulfate, risperidone, clonazepam, nefazodone, lovastatin, simvastatin, pravachol, ketorolac, hydromorphone, ticlopidine, seligiline, alprazolam, divalproex and phenytoin.

16. The method as claimed in claim 15, wherein said uncrosslinked polymers are selected from the group consisting of hydroxyethyl cellulose, ethylcellulose and hydroxypropylmethyl cellulose.

17. The method as claimed in claim 13, wherein said covalently crosslinked polymer is Carbopol® 934P NF or Carbopol® 971PNF.

18. The method as claimed in claim 13, wherein said uncrosslinked linear polymers are selected from the group consisting of Natrosol 250HHX, Ethylcellulose and Methocel K100M CR.

19. The method as claimed in claim 13, wherein said granulating solution is isopropyl alcohol.

20. The method as claimed in claim 13, wherein said wet granules are dried to a loss of drying of about less than 2%.

21. The method as claimed in claim 13, wherein said glidant is talc and said lubricant is magnesium stearate.

22. The method as claimed in claim 13, wherein said tablets have a hardness of 3.0 Strong Cobb units and friability of less than about 2%.

23. A pharmaceutical composition comprising;
- about 1 to 80% by weight pharmaceutically active agent;
- about 1 to 80% by weight covalently crosslinked water insoluble water swellable polymers; and
- about 1 to 75% by weight uncrosslinked, linear water soluble polymers.

24. The composition of claim 23, wherein said uncrosslinked polymers are selected from cellulose ethers and their derivatives.

25. The composition of claim 21, wherein said covalently crosslinked polymers are selected from water swellable, high molecular weight cross-linked homopolymers and copolymers of acrylic acid.

26. The composition of claim 21, wherein said cellulose ethers and their derivative are selected from the group consisting of hydroxyethyl cellulose, hydroxypropyl methyl cellulose, ethylcellulose and hydroxypropyl cellulose.

27. The composition of claim 23, wherein said covalently crosslinked water insoluble polymer is selected from polymers of acrylic acid crosslinked with polyalkenyl alcohols and divinyl glycol and mixtures thereof.

28. The composition of claim 23, wherein said composition additionally comprises about 0.5 to 50% by weight of a pharmaceutically acceptable film coating comprising anionic polymers based on methacrylic acid and methacrylic acid esters or neutral methacrylic acid esters with trimethylammonioethyl methacrylate chloride or cellulose esters.

29. The composition of claim 23, wherein said pharmaceutically active agent is selected from the group consisting of diltiazem, buspirone, tramadol, gabapentin, verapamil, etodolac, naproxen, diclofenac, COX2 inhibitors, budesonide, venlafaxine, metoprolol, carbidopa, levodopa, carbamazepine, ibuprofen, morphine, pseudoephedrine, paracetamol, cisapride, pilocarpine, methylphenidite, nifedipine, nicardipine, felodipine, captropril, terfenadine, pentoxifylline, fenofibrate, flipizide, aciclovir, zidovudine, moclobemide, potassium chloride, lamotrigine, citalopram, cladribine, loratadine, pancrelipase, lithium carbonate, orphenadrine, ketoprofen, procainamide, ferrous sulfate, risperidone, clonazepam, nefazodone, lovastatin, simvastatin, pravachol, ketorolac, hydromorphone, ticlopidine, seligiline, alprazolam, divalproex and phenytoin.

30. A pharmaceutical composition comprising :
- about 1 to 80% pharmaceutically active agent;

- about 1 to 60% by weight of hydroxyethylcellulose;
- about 1 to 75% by weight of hydroxypropylmethyl cellulose;
- about 1 to 60% by weight of ethylcellulose;
- about 1 to 80% by weight of at least one Carbopol® resin;
- about less than 10% by weight of talc;
- about less than 10% by weight of magnesium stearate; and
- about less than 95% by weight granulating and tableting aids.

31. The composition of claim 30, wherein said tabletting and granulating aids are selected from the group consisting of silicone dioxide, lactose, microcrystalline cellulose, calcium phosphate and mannitol.